

**PREPARING MERIT REVIEW PROPOSALS FOR SUBMISSION TO  
REHABILITATION RESEARCH AND DEVELOPMENT SERVICE****1. GENERAL**

a. **Forms and Instructions.** An investigator who plans to submit a pilot study proposal or full research proposal to Rehabilitation Research and Development Service (RR&D) for Merit Review needs to contact the Associate Chief of Staff (ACOS) for Research & Development (R&D) at the local Department of Veterans Affairs (VA) medical facility to obtain information concerning forms and instructions. For pilot study proposals, submit the original and twenty-five copies following the same format used for full research proposals.

b. **Number of Submissions.** No proposal should be submitted to more than one VA R&D Service at a time. Principal investigators (PIs) with an ongoing research project or program in any of the VA R&D Services who wish to explore an additional research proposal may submit a proposal to RR&D, subject to Letter of Intent (LOI) approval.

c. **Human Subjects.** If the proposed project involves the participation of human subjects, a Report of the Institutional Review Board (IRB) VA Form 10-1223, Report on Subcommittee on Human Studies, is required, as well as VA Form 10-1086, VA Research Consent Form.

d. **Experimental Devices and Investigational Drugs.** Clinical studies that include the use of experimental devices or drugs of unproven safety and efficacy are subject to both VA and Food and Drug Administration (FDA) regulations. For clinical investigations involving experimental devices or investigational drugs, an Investigation Exemption application must be submitted to FDA prior to submission of the proposal to RR&D (see VHA Handbook 1200.5).

e. **Withdrawing a Proposal.** If an investigator wishes to withdraw a proposal, RR&D must be notified promptly by telephone, followed by a memorandum addressed to the Director, RR&D Service.

f. **Transfers.** When a PI with a pending Merit Review proposal transfers to another VA facility, RR&D must be notified in advance of the transfer and must receive the required forms from the new VA facility (including approvals by the facility R&D Committee and appropriate subcommittees). The required forms must be received by RR&D in a timely manner for the proposal to be reviewed.

g. **Routing of Proposals.** Each proposal package is routed through the VA medical facility Office of the ACOS for R&D, the R&D Committee, the medical center Director and any other appropriate channels.

h. **Mailing of Proposals.** Proposals are to be sent to:

(1) Merit Review Proposal Coordinator  
Program Analysis and Review Section (122P)  
Rehabilitation Research and Development Service  
Department of Veterans Affairs  
810 Vermont Avenue, NW  
Washington, DC 20420

(2) Mailing address for express mail:

Merit Review Proposal Coordinator  
Program Analysis and Review Section (122P)  
Rehabilitation Research and Development Service  
Department of Veterans Affairs  
810 Vermont Avenue, NW  
Washington, DC 20420

***NOTE:** The telephone number is 202-254-0255.*

i. **Electronic Submission of Proposals.** In addition to the requirement for a hard copy, an electronic submission of each LOI is required as follows:

(1) The disk size must be 3 ½ in. The disk format may be high or low density (720K or 1.44 meg). It must be MS DOS, Windows, Windows 95-98, or NT formatted.

(2) The Brief Statement of Research Objectives (Abstract) must be file one on the disk. The file format must be plain text or Microsoft Word.

(3) Graphic pictures, drawings, etc. are not to be submitted electronically. Only the full text (narrative) of the proposal is required, and it must be file two on the disk. The file format must be plain text or Microsoft Word.

(4) The disk must be labeled with the date, PI's name, project number, and title. The disk must be included with the hard copy proposal submission.

**2. COMPONENTS OF APPLICATION PACKAGE:** Submit the following:

a. A typed single-spaced **original proposal**, one side only (unstapled). It will be used as the master file copy. ***NOTE:** May use black spring clips or rubber bands; do not use silver butterfly clips.* Attach an Optional Form 41, Routing and Transmittal Slip, with the station contact person and phone number.

b. **Ten copies** of VA Form 10-1313-1, Merit Review Application, and VA Form 10-1313-2, Summary Description of Program, duplicated back-to-back.

c. **Twenty-five copies** of the proposal duplicated back-to-back (stapled). If the proposal is too thick for a staple, then secure with a heavy black clip. Do not use silver butterfly clips. Check for proper page order.

d. **Six copies** of up to three selected papers that are representative of the applicant's best work (optional). Publications are not to be placed in an appendix; they need to be enclosed with, not attached to, the proposal.

e. A **memorandum** addressed to the Director, RR&D Service (122) with the names of two or more scientists who are qualified to review the proposal will be accepted. Information on reviewers must include their area of expertise and contact information (address, phone numbers, e-mail address, etc.). Include the name of any reviewer who may have a conflict of interest if asked to review your proposal.

f. If the proposal is a resubmission of a continuation project, a not-funded project, or a deferred project, **it is required** that six stapled copies of the previously reviewed proposal and six stapled copies of each reviewer's critique be included. Also include fifteen white copies of the Summary Statement from the previously reviewed proposal.

**3. PAGE FORMAT AND PAGE NUMBERING:** Submit the proposal on 8.5 x 11 inch paper, leaving a 1 inch margin on all sides. Where necessary, use a blank sheet of paper as a continuation sheet for the forms. Type material single-spaced in a type style that prints capital letters one-eighth (1/8) of an inch tall to ensure a clean imprint suitable for reproduction, scanning and readability. Type the PI's name in the lower right portion of each page, and number each page consecutively starting with the face sheet, e.g., Smith-1 to Smith-22. Prepare an index or table of contents and place after VA Form 10-1313-2.

**4. ORDER OF VA FORMS:** VA Forms 10-1313-1 through 10-1313-8 should be arranged in numerical order.

**5. VA FORM 10-1313-1, Merit Review Application:** Provide ten copies along with VA Form 10-1313-2.

Item 1: Insert **Letter of Intent** (LOI) number.

Item 2: **Leave blank.**

Item 3: Type in **proposal number** assigned by RR&D Service in large numbers.

Item 4: Type in **merit review round** (e.g., winter/year or summer/year).

Item 5: Complete.

Item 6: Provide the complete **mailing address** for the VA medical center or health care facility.

Item 7: **Social Security Number.** Complete for PI and Co-PI, if applicable.

Item 8: Provide the **date** the PI last submitted a proposal to RR&D for merit review.

Item 9: The last name of the **PI** needs to be typed first in capital letters, followed by the first name and initial(s). List telephone number(s) of the PI. The principal investigator needs to be the person responsible for the scientific and technical direction and completion of the work proposed (submission by a single PI is preferred; however, Co-PIs may be identified).

Item 10: The **proposal title** is not to exceed 72 typewritten spaces. Be specific and descriptive in the choice of title to assist readers in quickly identifying the overall program objectives. If the proposal title has been changed since a prior submission, or since the LOI was approved, print "NEW TITLE" directly above the typed title.

Item 11: The **amount requested** each year is to be the same as the totals listed on other forms within the application. The "total" is total funding requested for all years. Funds may be requested for a period of up to 3 years with a maximum of \$250,000 per year. **Proposals may not be submitted for more than 3 years.** *NOTE: Pilot proposals are limited to a maximum of \$50,000 and are funded for 1 year.*

Item 12: **VA employment status** refers to current or projected salary status of the PI. PIs who have less than a 5/8 part-time appointment must have an eligibility exception in order to submit a proposal. A copy of the 5/8 exception (see App. A, subpar. 2i.) request and the Chief R&D Officer approval memo for each PI and Co-PI must be included with all copies of merit review proposals (including pilots). A current VA paid appointment of at least 5/8 time is required before a research project can be funded (see VHA Handbook 1200.15).

Item 13: Mark the appropriate box indicating the PI **salary source**.

Item 14: Check appropriate box for **NEW or ONGOING**. A proposal is considered "new" when it has never been submitted or reviewed by RR&D Service. A proposal is considered "ongoing" when it has been funded for a period of time (1, 2, or 3 years) by RR&D Service. It may also be ongoing (continuation) even though it acquires a new title or there is a major shift in programmatic objectives. **In the blank space next to the ONGOING box include entire proposal number and previous review date, (i.e., A2672R; 1/99).** If a proposal is a resubmission of an unfunded application, type "Resubmission" in the blank space and list the proposal number and review date. If this application is a pilot, indicate "Pilot" in the blank space at the bottom of item 14. Because each RR&D proposal is considered separately, "No. of Projects in Program" should be one.

Item 15: **Program Code and Cost Center:** Insert the three-digit Program Code (**822** for RR&D) and the Cost Center number (**8122** for RR&D).

Item 16: Insert the primary research program area and primary specialty area. *NOTE: Primary specialty area is primary board or graduate field of study.*

Items 17 and 18: Complete for each PI and Co-PI.

Item 19: Complete and ensure that designated items are included in the proposal.

Item 20: Beginning with the current year of VA funding, complete and identify the VA Service from which **research support** is received. Provide the same information for non-VA funding.

Item 21: Complete for each PI and Co-PI. Insert the **date the PI entered on duty** at VA, or expected date of entry if appointment is pending. If there has been a break in service, list the

date of most recent appointment. You may indicate prior VA service as parenthetical information.

**Signature Blocks:** An original **signature** for the PI(s) and the ACOS for R&D (or designee) is required, with current date. By signing this VA form, the ACOS for R&D certifies that the proposal is complete administratively and all required reviews have been conducted. **Print or type beside or below the signature the name and phone number of a person to contact if administrative issues arise.**

## 6. VA FORM 10-1313-2, Summary Description of Program

a. **Identifying Information.** Check the box marked “project” to indicate that you are describing a project. Provide the identifying information requested: PI name; project title (72 characters or spaces maximum); and key words from the National Library of Medicine permitted Medical Subject Headings (MeSH).

b. **Brief Statement of Research Objectives (Abstract).** The primary purpose of this section is to provide a brief and accurate overview of the proposal. It should include: the research, development, evaluation program objectives (immediate and ultimate), the significance of the research to the VA health care system, and the general research design. A clear, concise description of the proposed study should be provided, however, technical details should not be included. List key words that best describe the scientific disciplines encompassed and the research areas addressed by the research.

**7. TABLE OF CONTENTS:** List all proposal items and sections, including but not limited to, narrative section; specify page numbers for each major proposal component and element of the proposal (include each part of the Appendix). The Table of Contents is to be inserted immediately after VA Form 10-1313-2.

## 8. VA FORM 10-1313-3, Current Funds and First Year Request

a. Check the appropriate box to indicate this form applies to a **project** and insert the identifying information (PI(s) name and project title).

b. List all **personnel** involved in the project, including the PI, under the block titled “PERSONNEL.” Provide their names and identify their degree(s).

(1) Secretaries are not allowed as study personnel.

(2) Intergovernmental Personnel Agreements (IPAs) are discouraged. If such arrangements are absolutely necessary for the successful implementation of the project, strong justification with a detailed explanation of estimated costs is required. Identify the name, role in the program and percent of effort under project personnel. Do not include cost. Also identify these IPA personnel under “ALL OTHER EXPENSES” with the title “IPA.” The projected cost should be under the section “FIRST YEAR REQUESTED FUNDS.”

c. Under the block titled “**ROLE IN PROGRAM**” identify for each person their role (i.e., PI, Co-PI, investigator, research technician, programmer analyst) and identify their grade and step.

d. List the **percent of total professional or technical effort** devoted to the project by all personnel identified.

(1) List costs for all personnel, which should be proportional to the time devoted to the project. Do not include cost-of-living increases, within grade increases, or anticipated promotions in the personnel category. All personnel projections need to be straight-lined for the duration of the project.

(2) List a **subtotal for the personnel dollars** requested.

e. The **first year request** column needs to include all RR&D funds being requested for the projected first 12 months of the project.

f. The **Current Year Funding** column needs to include RR&D funds available to the investigator for the 12-month period preceding the first year request if this proposal is an ongoing or continuation project.

g. If the services of a **consultant** are required, PIs need to consider current applicable VA rules and regulations before developing their budgets. Any consultant paid \$500 or more per consultation, exclusive of expenses, or \$2,500 or more per year must be approved by the Secretary, Department of Veterans Affairs.

(1) For each consultant listed, **provide a justification** on VA Form 10-1313-4, Estimated Expenses for Each Year, that indicates the nature of the service to be performed, the fee for each consultation, the amount of travel and per diem, and the number of consultations.

(2) Expenses related to the consultation, not including payment for services (i.e., **travel expenses**), should be listed under “ALL OTHER EXPENSES.” Travel expenses for non-government personnel should be identified separately from travel for government employees.

(3) Include **with the letters of endorsement** at the end of the proposal a letter from each person agreeing to consult and detailing the nature of the consultation. A curriculum vitae for each proposed consultant needs to be included.

h. List each item of **equipment** to be purchased and provide justification on VA Form 10-1313-4 for any item for which a need may not be apparent to reviewers or which costs more than \$3,000. For major equipment items, indicate how many similar instruments are located at the facility or in nearby laboratories and/or research areas. Do not submit manufacturer’s brochures or photocopies as part of the application. All charges for equipment maintenance must be justified.

i. List **supplies** by major types, such as: office supplies, animal supplies, etc.

j. List **all other expenses** by major category, including rental and contractual fees.

(1) IPAs are to be listed here if requested.

(2) Travel costs, including local travel, are permitted for project staff **if the travel is related directly to the conduct of the research**. List and justify any such travel explicitly on VA Form 10-1313-4. The travel estimate for government employees should be listed separately from any travel needs of non-VA personnel or consultants.

(3) Travel costs and registration fees for scientific meetings are **not** to be included (see App. G).

(4) Expenses for books, journals and professional organization dues are not permitted. Chargeback costs, as well as costs for manuscript preparation, photocopying, printing, publication, and illustrations are not allowed.

(5) Include the total acquisition charges for animal subjects (type, number, per diem) and total charges for Animal Research Facility maintenance of all animal subjects as itemized on the "ANIMAL COMPONENT OF RESEARCH PROTOCOL" statement.

## 9. VA FORM 10-1313-4, Estimated Expenses for Each Year

a. Check the appropriate box to indicate this form applies to a **project**.

b. The total **operating expenses** for the first year need to be identical to the total indicated on VA Form 10-1313-3, Current Funds and First Year Request, for this project. All differences in the operating expenses between years need to be fully justified in the space provided.

c. Provide detailed **justification** for all budget items listed on VA Form 10-1313-3. Use continuation sheets if necessary.

(1) Detailed descriptions of staff roles are not needed here, but need to be included in the project management plan in the text of the proposal. However, indicate total FTE requested each year. Indicate whether personal service estimates include fringe benefits, etc.

(2) Travel estimates need to be broken out by year, with a clear distinction between travel to be made by VA and other government employees and travel by non-VA consultants, etc. Government employee travel estimates are to be based on contract airfares and CONUS per diem rates.

(3) Where appropriate, provide a breakdown of the project budget by phases and year.

**10. VA FORM 10-1313-5, Biographic Sketch.** Complete for each investigator and collaborator on the project. Begin with the PI, and any Co-PIs, followed by Co-PIs and other key professional staff (i.e., include all persons who will participate in the design, performance, and professional direction of the proposed research, excluding consultants). Do not include curriculum vitae, either in addition to or in place of VA Form 10-1313-5.

**11. VA FORM 10-1313-6, Bibliography.** Complete this form for each investigator and collaborator (everyone with a VA Form 10-1313-5). Do not exceed two pages for each investigator and include a chronological list of all the most important and pertinent publications. Abstracts are to be separated from the publications. Do not include publications in preparation or presentations. Use the bibliographic format that has been used for the Research Development Information System (RDIS). Identify those publications that are a result of the most recent period of VA research support, and list them after the collaboration section of the narrative. Literature citations must include the full title of the paper being referenced. If there are no entries on VA Form 10-1313-6, “NONE” should be entered. Do not include curriculum vitae in addition to or in place of VA Forms 10-1313-5 and 10-1313-6.

**12. VA FORM 10-1313-7, Total VA and Non-VA Research Support, and VA FORM 10-1313-8, Total VA and Non-VA Research/Development**

a. Complete these forms for each investigator and collaborator on the project (each person with a VA Form 10-1313-5 and 10-1313-6 who is listed on VA Form 10-1313-3) with an effort of 10 percent and greater.

b. Every item listed on VA Form 10-1313-7 must be fully discussed on VA Form 10-1313-8. **Simple statements** such as “there are no budgetary, scientific or administrative overlaps” are not acceptable.

c. **Pending requests** must also be included even if there is no current support. Identify the Service and complete RR&D assigned project number, if applicable.

**13. NON-VA APPLICATIONS:** The abstract of the research plan and budget pages for all funded or pending non-VA applications are to be placed after VA Form 10-1313-8.

**14. RESUBMISSION:** A resubmitted proposal must include a letter (addressed to the Director, RR&D Service), of not more than three pages, that addresses each concern of the Board Summary Statement. State in detail what changes were made and how it compares to the previous proposal. This letter is to precede the narrative. The new text or changes from the previous proposal are to be reflected in the resubmission in italics. Also include six stapled copies of the latest related reviewed proposal and reviewers’ reports (critiques). Include fifteen copies of the Board Summary Statement.

**15. NARRATIVE DESCRIPTION:** The importance of a well-written, detailed, concise narrative description (not to exceed eighteen pages) cannot be overemphasized. The proposal must be complete for purposes of rigorous peer review without referral to previous proposal submissions, reviews, or extensive appendices, except when such appendices are deemed necessary to present progress of funded research for a continuation proposal.

a. **Rationale and/or Objectives of the Research**

(1) **Problem Statement.** Briefly define the problem or recognized need that the proposal is designed to address and include the scope and magnitude of the problem. Explain in the description the rationale for the study and the basis for such determination, with citation of



supportive and appropriate sources. Also cite other efforts undertaken in the respective research area, and why this particular effort is different and needed.

(2) **Hypotheses or Key Questions.** State the hypothesis or hypotheses to be tested or question(s) to be answered by the project.

(3) **Specific Objectives of the Project with a Projected Timetable.** A timetable needs to be provided to indicate expected progress of the study. Be as specific as possible. List the short and long-term objectives of this research. For long-term objectives, identify expected intermediate milestones. Identify an anticipated timetable for achievement of the short-term objectives. This timetable needs to represent a best estimate. It is recognized that early results may lead investigators to alter their specific objectives and timetable. Such alterations may be completely appropriate, but must be formally described and justified in a letter to the appropriate RR&D Program Analyst requesting approval.

(4) **Current Status.** Describe the current status of work that has been done toward solution of the problem(s) and how this work relates to the hypotheses or questions presented in subparagraph 15a(2) of this Appendix. This description should be sufficiently complete to demonstrate that the principal investigator is aware of all related research. Research supportive of and contrary to the hypotheses should be quoted and discussed. Care needs to be taken to keep this discussion concise and relevant to the problem(s), hypotheses, or questions.

(5) **Significance of Research.** Explain the potential research significance of the proposed study, both in general and with particular reference to the specific goals and priorities of VA. Identify any unique ideas or potential contributions that may result from this study. State the specific desired outcomes of the proposed study, i.e., how the particular method, concept or device may be transferred to the VA health care delivery system. Identify opportunities that VA may have to improve disabled veterans' quality of life and to contribute to the field of rehabilitation research and development.

(6) **Relevance of the Proposed Work to the VA Patient Care Mission.** In a separate paragraph, briefly indicate the relevance of the proposed work to the VA patient care mission and to problems of VA research.

b. **Background and Work Accomplished**

(1) For **completed pilot or continuation projects** (give title and entire project number; Box #3 of VA Form 10-1313-1) include a report of the progress made since the study's inception. The report needs to contain detailed information relative to the administrative and scientific completion of the project, whether or not the study met its stated goals, and summarize how funds were appropriately and efficiently used. For continuation projects, state the reasons why additional funds are being requested and provide a projected project completion date.

(2) Describe **accomplishments** to date. State the work done that is pertinent to this proposal. Provide reasons why this research is needed. State how it differs from or adds to work previously completed in this field. Charts, graphs, tables, figures, or other material need to be included that succinctly present significant data. These are **not** included in the eighteen-page

count for the narrative, but are not to exceed three pages. References are not to exceed four pages, for a grand total of **no more than twenty-five pages**. List all major publications resulting from work done during the period being reported. Do not include clinical case reports, summaries, or verbatim records of lectures, review articles, or abstracts of papers presented at meetings. Submit six copies of each pertinent paper (no more than three) to support progress (see subpar. 2d).

c. **Work Proposed**

(1) **Methodology**. Give details of the research plan including descriptive examples of the type of experiments or other work proposed, the major methods to be used, including the specific techniques, e.g., instrumentation, statistical methods to be employed, the kinds of data to be obtained, and the statistical analyses to be used.

(a) Studies involving human subjects must describe subject selection criteria with details concerning specific inclusion and/or exclusion factors. Informed consent is mandatory. A copy of the proposed informed consent form (ICF) must be included (see VHA Handbook 1200.5 for specific ICF instructions).

(b) When animals are going to be used in the project, list the number and type, including strains and species. Rationale for choosing the specific species and number must be addressed in the animal component form (ACF), which must be included (see VHA Handbook 1200.07 for specific ACF instructions).

(2) **Resources**. Describe the facilities and personnel required for the project. Indicate which are available and which must be obtained, including office and laboratory space, data processing facilities, clinical research wards, access to specific patients, access to VA staff, animal rooms, and major equipment and/or supply items.

(3) **Collaboration**. Describe any proposed collaboration with institutions and investigators. Include a description of the role of additional professional persons.

(4) **Literature References**. Cite key references and list full title, authors, and dates of publications. Include complete titles of articles as well as books and journals.

**16. LETTERS OF ENDORSEMENT:** Formal letters from the following must be attached to an RR&D proposal:

a. **The Director of the PI's VA Health Care Facility**. The letter must contain statements that:

(1) The Director understands the potential impact of the proposed research on the facility's organization

(2) The Director endorses the proposed project, and

(3) The space and necessary support of the VA facility will be available if the project is approved for funding by RR&D Service.

b. **The Appropriate Official of any Collaborating Institution.** The letter must contain the same information as required in preceding subparagraph 16a(1), subparagraph 16a(2) and, if appropriate, subparagraph 16a(3).

c. **Chairman of the Local VA R&D Committee.** A letter indicating the proposal has been reviewed and endorsed by the Chairman of the local VA R&D Committee.

d. **Organizational Elements.** An indication of concurrence from each participating or affected organizational element is required.

e. **Consultant(s) or Collaborator(s).** The specific role each individual named as a consultant or collaborator has in the project needs to be detailed. A curriculum vitae of each consultant is required.

**17. INQUIRIES AND ADDITIONAL INFORMATION:** Inquiries may be directed to RR&D Service, Program Analysis and Review Section (PARS), at (202) 254-0255. Refer also to the RR&D website at [www.vard.org](http://www.vard.org).